

(19)

Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 0 554 996 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
16.10.1996 Bulletin 1996/42

(51) Int. Cl.⁶: **A61M 5/31**, A61M 5/315

(21) Application number: **93300526.6**

(22) Date of filing: **25.01.1993**

(54) Medication delivery pen with improved dosage setting

Injektionsstift mit verbesserter Dosiereinrichtung

Crayon à injection avec moyen de dosage amélioré

(84) Designated Contracting States:
DE FR GB IT

(30) Priority: **04.02.1992 US 830816**

(43) Date of publication of application:
11.08.1993 Bulletin 1993/32

(73) Proprietor: **Becton Dickinson and Company**
Franklin Lakes, New Jersey 07417-1880 (US)

(72) Inventor: **Balkwill, David**
F-44000 Nantes (FR)

(74) Representative: **Ruffles, Graham Keith**
MARKS & CLERK,
57-60 Lincoln's Inn Fields
London WC2A 3LS (GB)

(56) References cited:
DE-A- 4 013 769 **US-A- 3 815 785**
US-A- 4 973 318

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

EP 0 554 996 B1

Description

BACKGROUND OF THE INVENTION

1. Field of the Invention. The field of the invention relates to medication delivery pens including dosage setting means.

2. Brief Description of the Related Art. A number of devices have been developed for administering insulin, drugs or other substances to persons and animals. As self-administration of certain substances, such as insulin, is common, it is important that devices designed for self-administration be simple to operate, reliable and accurate.

U.S. Patent No. 4,883,472 discloses an injection device which is capable of dispersing the contents of a pre-filled cartridge by advancing the piston within the cartridge by a selected amount. A displacing sleeve is provided for axially displacing a gear element by a constant stroke. The sleeve is moved in the advancing direction against the force of a spring, and is moved back to a rest position by the spring. A threaded rod may be axially advanced with respect to the gear element in order to set the desired dosage. The rod engages the cartridge piston when the sleeve is advanced, thereby advancing the piston by a selected distance corresponding to the selected dosage.

U.S. Patent No. 4,865,591 discloses another injection device which, unlike that disclosed in U.S. Patent No. 4,883,472, controls the dosage by allowing the stroke of a drive member to be varied. The distance traveled by the drive member corresponds to that traveled by the piston within an insulin cartridge. The dosage is displayed through a port in the body of the pen. The port is positioned adjacent to a scale including indicia corresponding to dosage units.

U.S. Patent No. 4,973,318 discloses another injection device in which the dosage administered corresponds to the distance traveled by the actuating member. A coarse dosage indicator is centrally located on the device, and provides an indication of smaller dosage units.

U.S. Patent No. 5,017,190 discloses an injection device including a circumferential measuring scale which provides an indication of the individual steps of a ratchet as adjustment means are turned. A longitudinal measuring scale is provided on a piston rod and indicates the dosage amount.

SUMMARY OF THE INVENTION

It is an object of the invention to provide such a device which allows the dosage to be easily set by the user and wherein the set dosage is displayed in a convenient and readily visible manner.

A still further object of the invention is to provide an injection device including a dosage dialing mechanism which can be turned in either of two directions in order to increase or decrease a dosage.

In accordance with these and other objects of the invention, an injection device is provided which includes an elongate housing, means for mounting a cartridge of the type including an internal piston to the housing, a piston rod movably mounted within the housing for engaging a cartridge piston when a cartridge is mounted to the housing for displacing fluid from the cartridge, and dose setting means for selecting the amount of fluid to be delivered by the device. The dose setting means includes a units counter ring, a tens counter ring positioned in adjoining relation to the units counter ring, and transmission means for connecting the units counter mean and the tens counter ring. The transmission means includes means for causing the tens counter ring to rotate a selected number of degrees upon rotation of the units counter ring through a selected angular displacement. The device also includes means responsive to the dose setting means for controlling the axial movement of the piston rod so that the distance the piston rod can be moved is dependent upon the rotational position of the units and ten counter rings.

In accordance with another embodiment of the invention, an injection device as described hereinabove, further includes a plunger portion of the piston positioned at least partially within the housing and a lead screw portion of the piston positioned at least partially within the plunger and axially slidable therein. The device includes a means for threadably engaging the lead screw and means for selectively moving the means for threadably engaging the lead screw into and out of engagement with the lead screw so that the lead screw is freely slidable with respect to the plunger when the means for threadably engaging the lead screw is disengaged from the lead screw. The lead screw and the plunger are slidable as a unit with respect to the housing when the means for threadably engaging the lead screw is engaged with the lead screw.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an injection device according to the invention;

Fig. 2 is a perspective view thereof showing the device in a zero position;

Fig. 3 is a perspective view thereof showing the plunger moving axially during an injection;

Fig. 4 is a perspective view thereof wherein the medication cartridge assembly is removed;

Figs. 5a and 5b are exploded perspective views of the device shown in Fig. 1 further including a needle assembly;

Fig. 6 is a partially enlarged detailed perspective view of the cartridge housing taken along lines 6-6 as shown in Fig. 5a;

Fig. 7 is a cross sectional view taken along lines 7-7 as shown in Fig. 1;

Fig. 8 is a cross sectional view taken along lines 8-8 as shown in Fig. 2;

Fig. 9 is a cross sectional view taken along lines 9-9 as shown in Fig. 4;

Fig. 10 is an enlarged cross sectional view of a zero detection clip of the device taken along lines 10-10 as shown in Fig. 5b; and

Fig. 11 is a cross sectional view thereof taken along lines 11-11 as shown in Fig. 10.

DETAILED DESCRIPTION OF THE INVENTION

An injection device 10 for injecting insulin or other medication is provided by the invention. As shown in Figs. 1-3, the device includes an adjusting knob 12, an upper body 14, a center body 16, and a transparent housing 18. All of these elements have a generally cylindrical configuration, and are arranged coaxially to define a generally cylindrical housing 20 which can easily be handled by a patient or medical attendant.

Referring to Figs. 5a, 5b and 7-9, a plunger 22 is at least partially positioned within the portion of the injection device housing 20 defined by the adjusting knob 12, upper body 14 and center body 16. The plunger includes a hollow, substantially cylindrical body 22a including a band of radially projecting ribs 22b extending outwardly therefrom. A pair of opposing projections 22c extend radially inwardly from the front end of the cylindrical body. The rear end of the plunger includes a pair of projections 22d which extend radially outwardly from the cylindrical body 22a.

The rear end of the plunger 22 is secured to a push button 24. The push button fits partially within the adjusting knob 12 when the plunger is fully inserted within the injection device housing 20.

A lead screw 26 is positioned within and coaxial with the plunger 22. The lead screw includes an enlarged front end 26a and a tapered rear end 26b which are connected by an elongate threaded body 26c. A pair of longitudinal grooves 26d are formed within the threaded body 26c. The grooves 26d receive the radially inwardly extending projections 22c of the plunger 22. The lead screw is accordingly rotatable with the plunger and capable of sliding axially with respect to the plunger.

A pair of half nuts 28 are positioned within the center body 16. Each half nut includes a semi-cylindrical body portion 28a and a radially enlarged end portion 28b. The front end of each half nut is threaded and is ordinarily threadably engaged with the lead screw 26.

The body portions 28a of the half nuts are positioned at least partially within a locking ring 30. The locking ring 30 includes a hollow, generally cylindrical body portion 30a which defines a generally elliptical passage for receiving the half nuts. The front end 30b of the locking ring is radially enlarged. A pair of projections 30c extend axially from the front end of the locking ring. The rear end of the transparent housing 18 (Fig. 6) includes a pair of opposing recesses 18a which are capable of receiving these projections.

A helical coil spring 32 is positioned over the locking ring 30 and half nuts 28. One end of the coil spring bears against the radially enlarged portions 28b of the half nuts while the opposite end thereof bears against the radially enlarged front end 30b of the locking ring. The front end 30b of the locking ring adjoins a radially inwardly extending band 16a on the center body 16. The rear ends of the half nuts abut the ribs 22b of the plunger 22, as shown in Figure 7.

The upper body 14 includes an opening in which a transparent window 34 is mounted. A units counter ring 36 and a tens counter ring 38 are positioned in adjoining relation beneath the window 34. Both counter rings include outer surfaces including numerals thereon. The numerals are visible through the window.

An O-ring 40 made from an elastomeric material is positioned between the upper body 14 and the units counter ring 36. A zero detection clip 42 is positioned between the inner surfaces of the units and tens counter rings and the outer surface of the plunger 22. The zero detection clip bears against the ribs 22b of the plunger when the spring 32 is in the position shown in Figs. 7 and 9. It bears against the enlarged end portions 28b of the half nuts when the spring is in the extended position, as shown in Fig. 8.

The inner surface of the units counter ring 36 is splined. This splined surface is engageable with the longitudinal ribs 22b of the plunger, which also function as splines. Such engagement occurs when the spring 32 is in the extended position shown in Fig. 8. The units counter ring 36 is also secured to the adjusting knob 12 such that rotation of the knob causes a corresponding rotation of the counter ring.

The zero detection clip 42, as best shown in Figs. 5b, 10 and 11, includes a generally cylindrical body 42a having a radially enlarged front end 42b. A lower spring member 42c extends axially within a slot formed within the clip body 42a. The lower spring member 42c includes a ridge 42d which is engageable with grooves 38a formed within the inner surface of the tens counter ring 38, as best shown in Fig. 11.

The zero detection clip 42 also includes an axially extending upper spring member 42e, the position of which is controlled by the rotational positions of the units and tens counter rings 36, 38. The upper spring member 42e includes an inner ridge 42f which is engageable with the ribs 22b of the plunger 22 when pushed into its active position by the units counter ring. The inner surface of the units counter ring functions as a cam in controlling the radial position of the upper spring member 42e of the zero detection clip 42.

A transmission key 44 is provided for engaging and disengaging the units and tens counter rings 36, 38. The key is located within a channel formed in the units counter ring, as shown in Fig. 9. It is held in place by the elastic ring 40. One end of the key 44 is engageable with a cam 14a provided within the upper body 14, as shown in Fig. 5b. The other end thereof is engageable with slots 38b formed within the tens counter ring 38.

The configurations of the cam 14a, the slots 38b, and the end of the key engageable with the slots is the same, i.e., triangular.

The transparent housing 18 is adapted for receiving a cartridge 46 of the type including an internal piston 46b and a pierceable seal 46a at one end thereof. Both ends of the transparent housing are threaded. One threaded end 18a is employed for connecting it to the center body 16. The other threaded end 18b is employed for securing a double ended needle assembly 50. Needle assembly 50 includes a cannula 50a having a sharp distal end 50b for piercing the skin of the user and a sharp proximal end 50c for piercing seal 46a of the cartridge and a lumen (not shown) therethrough. Needle assembly 50 includes a cup-shaped hub 50d holding said cannula so that the sharp proximal end projects outwardly from the interior of the cup-shaped hub. The cup-shaped hub includes an internal thread which is compatible with the thread at 18a so that the needle assembly may be removably attached to housing 18 with its sharp proximal end piercing pierceable seal 46a to establish fluid communication between said lumen and the interior of said cartridge.

The operation of the injection device 10 shall now be described with reference to the accompanying figures. Generally speaking, a cartridge is loaded within the device, and a double ended needle is affixed to the end of the transparent housing. Fluid communication is accordingly established between the injection portion of the double ended needle and the interior of the cartridge. Once the appropriate dosage is set, the push button 24 is urged forwardly, causing the lead screw 26 to exert pressure upon the piston movably positioned within the cartridge. The piston displaces fluid within the cartridge, causing its injection into body tissue through the double ended needle. The specific functions which are performed using the injection device are described separately herein. Assuming the device is loaded, three steps are followed in the injection procedure: set to zero, set the dose, and make the injection.

TO SET TO ZERO

The adjusting knob 12 is rotated back to the zero setting on both counter rings 36 and 38. As will be described in more detail hereinbelow, the adjusting knob turns the units counter ring 36 and the tens counter ring 38. Because the splines on the units counter ring 36 and the plunger 22 are disengaged, as shown in Fig. 7, the plunger 22 and the lead screw 26 do not turn. When the rings reach zero, their slots align as shown in Fig. 8 and release the upper spring member 42e of the zero detection clip 42. This in turn releases the plunger 22 and push button 24 which move open under pressure from the spring 32 through the two half nuts 28 until the nuts reach the stop on the zero detection clip 42. This movement also carries the lead screw 26. The ribs 22b on the plunger 22 engage with the splined units counter ring 36 ready for setting a dose.

TO SET THE DOSE

The adjusting knob 12 is rotated away from the zero (0) setting. The adjusting knob turns the units counter ring 36, which turns the plunger 22. The plunger 22 is engaged with the longitudinal grooves 26d in the lead screw 26 which turns and screws forward in the nut formed by the two half nuts 28. The lead screw's travel is proportional to the number of units displayed by the counter rings 36, 38.

TO MAKE AN INJECTION

When the desired dose has been set, the push button 24 is pushed fully in. The push button 24 pushes the plunger 22, the two half nuts 28, and the lead screw 26 forwards. The plunger and lead screw, as coupled by the half nuts, accordingly perform the function of a piston rod. The travel is determined by the bosses of the two half nuts 28 which slide in slots inside the center body 16 up to a stop defined by the rear end of the locking ring 30. The travel corresponds to the maximum dose which can be injected. The first part of the travel brings the end of the lead screw 26 into contact with the piston 46b of the cartridge 46; the second part of the travel moves the piston of the cartridge forward and delivers the measured amount of insulin. While setting the dose, the lead screw 26 is moved forward in proportion to the dosage set; this distance determines the proportion of the pre-injection and injection travel. The plunger and the push button are locked in position by the upper spring member of the zero detection clip 42 following an injection.

EXAMPLES

If the dose is set to 0 units, the lead screw 26 will not touch the piston of the cartridge until the end of the travel and no units will be injected. (Pre-travel 59 units, injection travel 0 units.)

If the dose is set to 59 units, the lead screw will touch the piston of the cartridge immediately and 59 units will be injected. (Pre-travel 0, injection travel 59.)

If the dose is set to "n" units, the lead screw will move forward 59-n units until it touches the piston of the cartridge, and then push the piston forwards 59-(59-n)=n units. (Pre-travel 59-n, injection travel n.)

DOSE SETTING FOR PARTIALLY SIGHTED USERS

When a dose is set, the units counter ring 36 pushes the upper spring member 42e of the zero detection clip 42 into its active position. The ridge 42f on its inner surface creates a click for each unit as it passes over the splines (ribs 22b) on the plunger 22. The units counter ring 36 drives the tens counter ring 38 through 36 degrees of rotation every time the units counter ring passes zero. The lower spring member 42c of the zero detection clip 42 has a ridge 42d which engages with

the grooves 38a inside the tens counter ring 38 and creates a click every time the tens counter ring 38 turns. The clicks of the two counter rings coincide every ten units, making an accentuated click to help partially sighted users.

LIMITATION OF DOSE

If the dose is set at 59 units, the tens counter ring 38 reaches a stop, and the transmission key 44 engages in the last location in the tens counter ring 38 as shown in Fig. 11. If the adjusting knob 12 is turned further, the rings 36 and 38 are unable to turn, and the adjusting knob 12 slips without further effect. The rounded shapes of the ribs 22b in the grooves (splines) of the units counter ring 36 limit the torque which will be transmitted to the counter rings and prevent unintentional damage.

LIMITATION OF DOSE TO THE REMAINING CAPACITY OF THE CARTRIDGE

The travel of the lead screw 26 is limited to the safe travel of the piston in the cartridge 46. If the lead screw 26 reaches the end of its travel, the projections 22c inside the plunger 22 reach the end of the grooves 26d in the lead screw 26 and prevent it from further movement. The lead screw 26 prevents the plunger 22 and the counter rings 36 and 38 from turning. The adjusting knob 12 will then slip without further effect. The counter rings will indicate the travel of the lead screw to this point, and, therefore, the quantity of insulin remaining in the cartridge.

CHECKING THE REMAINING CAPACITY OF THE CARTRIDGE

The adjusting knob 12 is rotated away from the zero (0) setting. If there are more than 59 units remaining in the cartridge, the counter rings will stop at 59 units as described above. If there are less than 59 units remaining, the counter rings will stop as described above and display the remaining capacity of the cartridge.

In either case, the user can then turn the adjusting knob 12 towards himself until the counter rings display the dose to be administered.

CHANGING THE CARTRIDGE

After a complete injection has been made, the push button 24 is left in the locked position. The transparent housing 18 is unscrewed and the cartridge is removed.

The transparent housing 18 has two recesses 18a which engage with the projections 30c extending from the locking ring 30. When the transparent housing 18 is unscrewed, the locking ring 30 is turned through 90 degrees before disengaging. The locking ring 30 meets two stops 16a inside the center body 16 which prevent it from turning further.

The elliptical shape defined by the inner wall of the locking ring 30 allows the two half nuts 28 to open under pressure from the spring 32 and to free the lead screw 26 as shown in Fig. 9.

A new cartridge 46 is inserted into the transparent housing 18 which is then screwed into place. As the transparent housing 18 moves towards the center body 16, the piston of the cartridge will push the lead screw 26 into the device. About 90 degrees before the end of its travel, the two recesses of the transparent housing 10 engage with the projections of the locking ring 30 and turn it through 90 degrees. The locking ring 30 meets the two stops inside the center body 16 which prevent it from turning further. The elliptical inner wall of the locking ring 30 moves the two half nuts 28 into engagement with the lead screw 26. The thread profile is adapted to this engagement.

The position of the lead screw 26 is determined by the position of the piston in the cartridge. When the first dose is set, the lead screw 26 will be in the correct relative position to make an immediate injection. It is thus possible to load partially filled cartridges if desired.

OPERATION OF THE COUNTER RINGS

The upper body 14 houses the four parts which comprise the counter mechanism. The window 34 in the upper body 14 shows the numbers printed on the outside of the two counter rings 36 and 38, and indicates the number of units to be injected from 0 to 59.

The units counter ring 36 is turned by the adjusting knob 12. When the units counter ring 36 has turned to numbered position "8", the transmission key 44 meets the cam 14a molded inside the upper body 14. The transmission key 44 is forced to slide up the face of the cam, and reaches the top in position "9". The elastic ring 40 is deformed by this movement and maintains the transmission key 44 in contact with the cam. This movement also brings the opposite end of the transmission key 44 into engagement with one of the slots 38b inside the tens counter ring 5.

When the units counter ring 36 is turned further, the transmission key 44 transmits the movement to the tens counter ring 38, and the two rings turn together. At position "10" the window 34 now displays "10". At this point, the transmission key 44 has rotated 36 degrees to the end of the raised face of the cam inside the upper body 14.

If the units counter ring 36 is turned further, the transmission key 44 is free to slide down the face of the cam 14a inside the upper body 14 under pressure from the elastic ring 40. This movement disengages the two counter rings, and the counter will now read "11".

This movement is repeated each time the units counter ring 36 moves from position "8", through positions "9" and "0" to position "1". The reverse procedure is identical.

The tens counter ring 38 has stops in the "0" and "5" positions to prevent the counter mechanism from

going beyond a maximum reading of 59 or a minimum reading of 0 units. In both of these positions the transmission key 44 is in its active, engaged position, which explains why it has seven slots.

It should be noted that if the stops for the tens counter ring 38 were moved, the reading could continue up to 99 units.

OPERATION OF THE ZERO DETECTION CLIP

The upper spring member 42e of the zero detection clip 42 is the key to the alternate "count/reset" movement of the injection device 10.

The upper spring member 42e pushes up in its relaxed position, as shown in Fig. 8. The two counter rings 36 and 38 have slots which align in the zero (0) setting position and which allow this movement.

The slot in the units counter ring 36 has an angled face which works as a cam, forcing the upper spring member 42e down into its active position as soon as the units counter ring 36 leaves the "0" position. The units counter ring 36 holds the zero detection clip 42 in its active position up to position "9". In position "10" the tens counter ring 38 has moved, and now holds the zero detection clip 6 in its active position. From position "10" to position "59" the zero detection clip 42 is held in its active position by the tens counter ring 38. Fig. 7 illustrates the engagement of the tens counter ring with the spring member 42e, while Fig. 9 illustrates the engagement of the units counter ring therewith.

In its active position, the underside of the zero detection clip 42 is in contact with the splines (ribs 22b) on the plunger 22. The ridge 42f under the upper spring member fits between the ribs 22b and ensures their indexation. The ridge 42f also makes the click sound as each rib 22b passes while a dosage adjustment is made. When an injection is made, the plunger 22 slides through the zero detection clip 42 until the ends of its travel. At this point the end of the upper spring member 42e drops behind the end of the rib 22b and prevents the plunger 22 from moving out under pressure from the spring 32. The components can be designed so that this movement will make a clicking sound, confirming that a complete injection has been made.

When the counter is set to "0" as shown in Fig. 8, the slots inside the two counter rings 36 and 38 align with the upper spring member of the zero detection clip 42 and allow it to spring up into its rest position. This movement frees the plunger 22 and allows a new dose to be set.

The injection device as constructed in accordance with the invention offers a number of desirable features which facilitate its use. The size of the device, including a relatively short length and small diameter, allows it to be easily carried and used. A clip (not shown) may be provided in order to secure the device to a pocket.

The cartridge 46 is easily loaded and substantially fully visible to the user. Two-way dosage adjustment is possible, which allows corrections to be made quickly

and easily. The dosage to be administered is clearly displayed and will remain displayed subsequent to the injection procedure. In order to insure that a complete injection has been made, the device produces a click and locks in the closed position only when the plunger is fully inserted.

Although illustrative embodiments of the present invention have been described herein with reference to the accompanying drawings, it is to be understood that the invention is not limited to those precise embodiments.

Claims

1. An injection device (10) for inserting selected dosages of fluid, comprising:

a elongate housing (18);
means for mounting a fluid containing cartridge (46) of the type including an internal piston (46b) to said housing (18);
a piston rod (22, 26, 28) movably mounted within the housing (18) for displacing fluid from a cartridge (46);
dose setting means (12) for selecting the amount of fluid to be delivered by said device (10); and
means (22b, 22c, 26d, 28, 30) responsive to said dose setting means for controlling the axial movement of said piston rod (22, 26, 28) such that the distance said piston rod (22, 26, 28) can be moved is dependent upon the rotational position of said units and tens counter rings (36, 38);
characterized in that the dose setting means (12) for selecting the amount of fluid to be delivered by said device (10) includes a units counter ring (36), a tens counter ring (38) positioned in adjoining relation to said units counter ring (36), and transmission means (14a, 38b, 44) for connecting said units counter ring (36) and said tens counter ring (38), said transmission means (14a, 38b, 44) including means for causing said tens counter ring (38) to rotate a selected number of degrees upon rotation of said units counter ring (36) through a selected angular displacement.

2. An injection device (10) as described in Claim 1 including means for disengaging said transmission means (14a, 38b, 44) from said tens counter ring (38) once said tens counter ring (38) has rotated through said selected number of degrees.

3. An injection device (10) as described in Claim 1 wherein said transmission means (14a, 38b, 44) include a transmission key (44) positioned within said housing (18) and means for urging said key (44) into engagement with said tens counter ring

(38) when said units counter ring (36) is in a selected rotational position.

4. An injection device (10) as described in Claim 3 including a plunger (22) connected to said piston rod (22, 26, 28) and extending through said units and tens counter rings (36, 38), and a zero detection clip (42) positioned at least partially between said plunger (22) and said units counter ring (36), at least one of said units and tens counter rings (36, 38) including means for urging said zero detection clip (42) into engagement with said plunger (22), thereby holding said plunger (22) in a selected axial position with respect to said housing (18), said units counter ring (36) being engaged to and rotatable with said plunger (22).
5. An injection device (10) as described in Claim 4 wherein said plunger (22) includes a plurality of elongate ribs (22b) extending radially outwardly therefrom, said zero detection clip (42) including means for engaging said ribs (22b) so that a clicking sound is produced as said plunger (22) is rotated with respect to said housing (18).
6. An injection device (10) as described in Claim 4 wherein said zero detection clip (42) includes a spring member (42e), at least one of said units and tens counter rings (36, 38) including means for urging said spring member into engagement with said plunger (22).
7. An injection device (10) as described in Claim 1 further including a elongate fluid-containing cartridge (46) having a internal piston (46b) at its proximal end and a pierceable seal (46a) at its distal end defining a reservoir for said fluid, said cartridge (46) being movably mounted in said device (10); and a needle assembly (50) including a elongate cannula and a cup-shaped hub (50d), said cannula having a sharp proximal end (50c), a sharp distal end (50b) and a lumen therethrough, said cup-shaped hub (50d) holding said cannula so that said sharp proximal end (50c) of said cannula projects outwardly from the interior of said cup-shaped hub (50d), said needle assembly (50) being removably attached to said device (10) so that said sharp proximal end (50c) pierces said pierceable seal (46a) of said cartridge (46) so that said lumen is in fluid communication with the fluid in said cartridge (46).
8. An injection device (10) as described in Claim 1 further comprising:
 - a plunger (22) portion of said piston rod (22, 26, 28) positioned at least partially within said housing (18);

a lead screw (26) portion of said piston rod (22, 26, 28) positioned at least partially within said plunger (22) and axially slidable therein;

means for threadably engaging said lead screw (26);

means for selectively moving said means for threadably engaging said lead screw (26) into and out of engagement with said lead screw (26), whereby said lead screw (26) is freely slidable with respect to said plunger (22) when said means for threadably engaging said lead screw (26) are disengaged from said lead screw (26), said lead screw (26) and plunger (22) being slidable as a unit with respect to said housing (18) when said means for threadably engaging said lead screw (26) are engaged with said lead screw (26).

9. A device (10) as described in Claim 8 wherein said means for threadably engaging said lead screw (26) include a pair of at least partially threaded half nuts (28) positioned in opposing relation to each other within said housing (18) with the threaded portion of said half nut facing said lead screw (26).
10. A device (10) as described in Claim 9 wherein said means for moving said half nuts (28) include a rotatable locking ring (30), said locking ring (30) including an elliptical inner wall, wherein rotation of said locking ring (30) causes said inner wall of said locking ring (30) to contact said half nuts (28) and move said half nuts (28) to a position wherein said threaded portion of said half nuts (28) contacts said lead screw (26).

Patentansprüche

1. Injektionsinstrument (10) zum Einführen von ausgewählten Dosen an Fluid, das folgende Komponenten aufweist:

ein längliches Gehäuse (18);

Mittel zum Anbringen einer ein Fluid enthaltenden Patrone (46) des Typs, der einen Kolben (46b) innerhalb des Gehäuses (18) einschließt; eine Kolbenstange (22, 26, 28), die beweglich innerhalb des Gehäuses (18) angebracht ist, um Fluid aus einer Patrone (46) zu verdrängen; ein Dosis-Einstellmittel (12) zur Wahl der Menge an Fluid, die durch das Instrument (10) abgegeben werden soll; und

Mittel (22b, 22c, 26d, 28, 30), die auf das Dosis-Einstellmittel ansprechen, um die Axialbewegung der Kolbenstange (22, 26, 28) zu steuern, derartig, daß die Strecke, über welche die Kolbenstange (22, 26, 28) bewegt werden kann, von der Rotationsposition von Einheiten- und von Zehner-Zählrings (36, 38) abhängig ist:

- dadurch gekennzeichnet, daß das Dosis-Einstellmittel (12) zur Auswahl der Menge an Fluid, die durch das Instrument (10) abgegeben werden soll, einen Einheiten-Zählring (36), einen Zehner-Zählring (38), der in Nachbarbeziehung zum Einheiten-Zählring (36) angeordnet ist, und Übertragungsmittel (14a, 38b, 44) einschließt, um den Einheiten-Zählring (36) und den Zehner-Zählring (38) miteinander zu verbinden, wobei die Übertragungsmittel (14a, 38b, 44) ein Mittel einschließen, das bewirkt, daß der Zehner-Zählring (38) um eine ausgewählte Anzahl von Graden notiert, nachdem der Einheiten-Zählring (36) um eine ausgewählte Winkelverschiebung gedreht worden ist.
2. Injektionsinstrument (10) nach Anspruch 1, das ein Mittel zum Lösen der Übertragungsmittel (14a, 38b, 44) vom Zehner-Zählring (38) einschließt, sobald sich der Zehner-Zählring (38) um die ausgewählte Anzahl von Graden gedreht hat.
 3. Injektionsinstrument (10) nach Anspruch 1, bei dem die Übertragungsmittel (14a, 38b, 44) eine Übertragungstaste (44), die sich innerhalb des Gehäuses (18) befindet, und Mittel einschließen, um die Taste (44) zum Eingriff mit dem Zehner-Zählring (38) zu drücken, wenn sich der Einheiten-Zählring (36) in einer ausgewählten Rotationsstellung befindet.
 4. Injektionsinstrument (10) nach Anspruch 3, das einen Plunger (22), der mit der Kolbenstange (22, 26, 28) verbunden ist und durch den Einheiten- und den Zehner-Zählring (36, 38) führt, und eine Null-Nachweis-Klammer (42) einschließt, die sich zumindest teilweise zwischen dem Plunger (22) und dem Einheiten-Zählring (36) befindet, wobei wenigstens einer der Einheiten- und Zehner-Zählringe (36, 38) Mittel einschließt, um die Null-Nachweis-Klammer (42) zum Eingriff mit dem Plunger (22) zu drücken, um so den Plunger (22) in einer ausgewählten Axialstellung im Verhältnis zu dem Gehäuse (18) zu halten, wobei der Einheiten-Zählring (36) mit dem Plunger (22) in Eingriff kommt und mit diesem drehbar ist.
 5. Injektionsinstrument (10) nach Anspruch 4, bei dem der Plunger (22) eine Vielzahl von Längsrippen (22b) einschließt, die von diesem radial nach außen verlaufen, daß die Null-Nachweis-Klammer (42) Mittel zum Eingriff mit den Rippen (22b) einschließt, so daß ein Klick-Ton erzeugt wird, wenn der Plunger (22) im Verhältnis zu dem Gehäuse (18) gedreht wird.
 6. Injektionsinstrument (10) nach Anspruch 4, bei dem die Null-Nachweis-Klammer (42) ein Federelement (42e) einschließt und wenigstens einer der Einheiten- und Zehner-Zählringe (36, 38) Mittel einschließt, um das Federelement zum Eingriff mit dem Plunger (22) zu drücken.
 7. Injektionsinstrument (10) nach Anspruch 1, das außerdem folgende Komponenten einschließt; eine längliche, ein Fluid enthaltende Patrone (46), die einen inneren Kolben (46b) an ihrem proximalen Ende und eine zu durchstechende Dichtung (46a) an ihrem distalen Ende hat und ein Reservoir für das Fluid definiert, wobei die Patrone (46) beweglich an dem Instrument (10) angebracht wird; und eine Nadel-Baugruppe (50), die eine längliche Kanüle und ein kappenförmiges Verbindungsstück (50d) einschließt, wobei die Kanüle ein spitzes proximales Ende (50c), ein spitzes distales Ende (50b) und eine hindurchführende Hohlrohre hat, wobei das kappenförmige Verbindungsstück (50d) die Kanüle so hält, daß das spitze proximale Ende (50c) der Kanüle aus dem Inneren des kappenförmigen Verbindungsstückes (50d) nach außen vorsteht, wobei die Nadel-Baugruppe (50) abnehmbar an dem Instrument (10) befestigt wird, so daß das spitze proximale Ende (50c) die zu durchstechende Dichtung (46a) der Patrone durchsticht, so daß sich die Hohlrohre mit dem Fluid in der Patrone (46) in Fluid-Verbindung befindet.
 8. Injektionsinstrument (10) nach Anspruch 1, das außerdem folgende Komponenten aufweist:
 - einer Plungerabschnitt (22) der Kolbenstange (22, 26, 28), der sich zumindest teilweise innerhalb des Gehäuses (18) befindet;
 - einen Leitspindelabschnitt (26) der Kolbenstange (22, 26, 28), der sich zumindest teilweise innerhalb des Plungers (22) befindet und in Axialrichtung darin gleiten kann;
 - Mittel zum Gewindeeingriff mit der Leitspindel (26);
 - Mittel zum selektiven Bewegen des Mittels zum Gewindeeingriff mit der Leitspindel (26) zum selektiven Eingriff mit der Leitspindel (26) und zum Lösen desselben, wodurch die Leitspindel (26) im Verhältnis zum Plunger (22) frei gleiten kann, wenn das Mittel zum Gewindeeingriff mit der Leitspindel (26) von der Leitspindel (26) gelöst ist, wobei die Leitspindel (26) und der Plunger (22) als eine Einheit im Verhältnis zum Gehäuse (18) gleiten können, wenn das Mittel zum Gewindeeingriff mit der Leitspindel (26) mit der Leitspindel (26) im Eingriff ist.
 9. Instrument (10) nach Anspruch 8, bei dem das Mittel zum Gewindeeingriff mit der Leitspindel (26) ein Paar von zumindest teilweise mit Gewinde versehene Schloßmuttern (28) einschließt, die in einem gegenüberliegenden Verhältnis zueinander innerhalb des Gehäuses (18) angeordnet sind, wobei

der Gewindeabschnitt der Schloßmuttern zur Leitspindel (26) hin zeigt.

10. Instrument (10) nach Anspruch 9, bei dem das Mittel zum Bewegen der Schloßmuttern (28) einen drehbaren Klemmring (30) einschließt, wobei der Klemmring (30) eine elliptische Innenwand einschließt, worin die Drehung des Klemmrings (30) bewirkt, daß die Innenwand des Klemmrings (30) mit den Schloßmuttern (28) in Kontakt kommt und die Schloßmuttern (28) in eine Position bewegt, in welcher der Gewindeabschnitt der Schloßmuttern (28) mit der Leitspindel (26) in Kontakt ist.

Revendications

1. Dispositif d'injection (10) pour injecter des dosages sélectionnés de fluide, comprenant:

une enveloppe allongée (18);
un moyen pour monter une cartouche contenant un fluide (46) du type incluant un piston interne (46b) sur ladite enveloppe (18);
une tige-piston (22, 26, 28) montée de manière mobile à l'intérieur de l'enveloppe (18) pour déplacer le fluide venant d'une cartouche (46);
un moyen de réglage d'une dose (12) pour sélectionner la quantité de fluide devant être délivrée par ledit dispositif (10); et
un moyen (22b, 22c, 26d, 28, 30) sensible audit moyen de réglage de la dose pour contrôler le mouvement axial de ladite tige-piston (22, 26, 28) de telle sorte que la distance sur laquelle ladite tige-piston (22, 26, 28) peut être déplacée soit fonction de la position de rotation des bagues de comptage des unités et des dizaines (36, 38);
caractérisé en ce que le moyen de réglage d'une dose (12) pour sélectionner la quantité de fluide devant être délivrée par ledit dispositif (10) comprend une bague de comptage des unités (36), une bague de comptage des dizaines (38) positionnée de manière adjacente à ladite bague de comptage des unités (36), et un moyen de transmission (14a, 38b, 44) pour relier ladite vague de comptage des unités (36) et ladite bague de comptage des dizaines (38), ledit moyen de transmission (14a, 38b, 44) comprenant un moyen pour amener ladite bague de comptage des dizaines (38) à effectuer une rotation correspondant à un nombre sélectionné de degrés lorsque ladite bague de comptage des unités (36) effectue une rotation couvrant un déplacement angulaire sélectionné.

2. Dispositif d'injection (10) selon la revendication 1, comprenant un moyen pour désaccoupler ledit moyen de transmission (14a, 38b, 44) de ladite

bague de comptage des dizaines (38) une fois que la bague de comptage des dizaines (38) a effectué une rotation sur ledit nombre sélectionné de degrés.

3. Dispositif d'injection (10) selon la revendication 1, dans lequel ledit moyen de transmission (14a, 38b, 44) comprend une clé de transmission (44) placée à l'intérieur de ladite enveloppe (18) et un moyen pour pousser ladite clé (44) à s'encliqueter avec ladite bague de comptage des dizaines (38) lorsque ladite bague de comptage des unités (36) est dans une position de rotation sélectionnée.
4. Dispositif d'injection (10) selon la revendication 3, comprenant un élément-plongeur (22) relié à ladite tige-piston (22, 26, 28) et s'étendant à travers lesdites bagues de comptage des unités et des dizaines (36, 38), et un collier de détection du zéro (42) placé au moins partiellement entre ledit élément-plongeur (22) et ladite bague de comptage des unités (36), au moins une desdites bagues de comptage des unités et des dizaines (36, 38) comprenant un moyen pour pousser ledit collier de détection du zéro (42) à s'encliqueter avec ledit élément-plongeur (22), maintenant ainsi ledit élément-plongeur (22) dans une position axiale sélectionnée par rapport à ladite enveloppe (18), ladite bague de comptage des unités (36) étant couplée avec ledit élément-plongeur (22) et pouvant tourner avec lui.
5. Dispositif d'injection (10) selon la revendication 4, dans lequel ledit élément-plongeur (22) est pourvu d'une pluralité de nervures allongées (22b) s'étendant radialement vers l'extérieur, ledit collier de détection du zéro (42) comprenant un moyen pour s'encliqueter avec lesdites nervures (22b) de manière à ce qu'un bruit de déclic soit produit lorsque l'on fait tourner ledit élément-plongeur (22) par rapport à ladite enveloppe (18).
6. Dispositif d'injection (10) selon la revendication 4, dans lequel ledit collier de détection au zéro (42) comprend un élément de ressort (42e), au moins une desdites bagues de comptage des unités et des dizaines (36, 38) comprenant un moyen pour pousser ledit élément de ressort à s'encliqueter avec ledit élément-plongeur (22).
7. Dispositif d'injection (10) selon la revendication 1, comprenant en outre une cartouche allongée (46) contenant un fluide, pourvue d'un piston interne (46b) à son extrémité proximale et d'une capsule transperçable (46a) à son extrémité distale, qui définissent un réservoir pour ledit fluide, ladite cartouche (46) étant installée de manière mobile dans ledit dispositif (10); et
un système d'aiguille (50) comprenant une canule allongée et une tulipe en forme de tasse

(50d), ladite canule possédant une extrémité proximale pointue (50c), une extrémité distale pointue (50b) et une lumière qui la traverse, ladite tulipe en forme de tasse (50d) maintenant ladite canule de manière à ce que ladite extrémité proximale pointue (50c) de ladite canule fasse saillie vers l'extérieur depuis l'intérieur de ladite tulipe en forme de tasse (50d), ledit système d'aiguille (50) étant fixé de manière amovible sur ledit dispositif (10) de manière à ce que ladite extrémité proximale pointue (50c) perce ladite capsule transperçable (46a) de ladite cartouche (46) afin que ladite lumière soit en communication fluide avec le fluide se trouvant dans ladite cartouche (46).

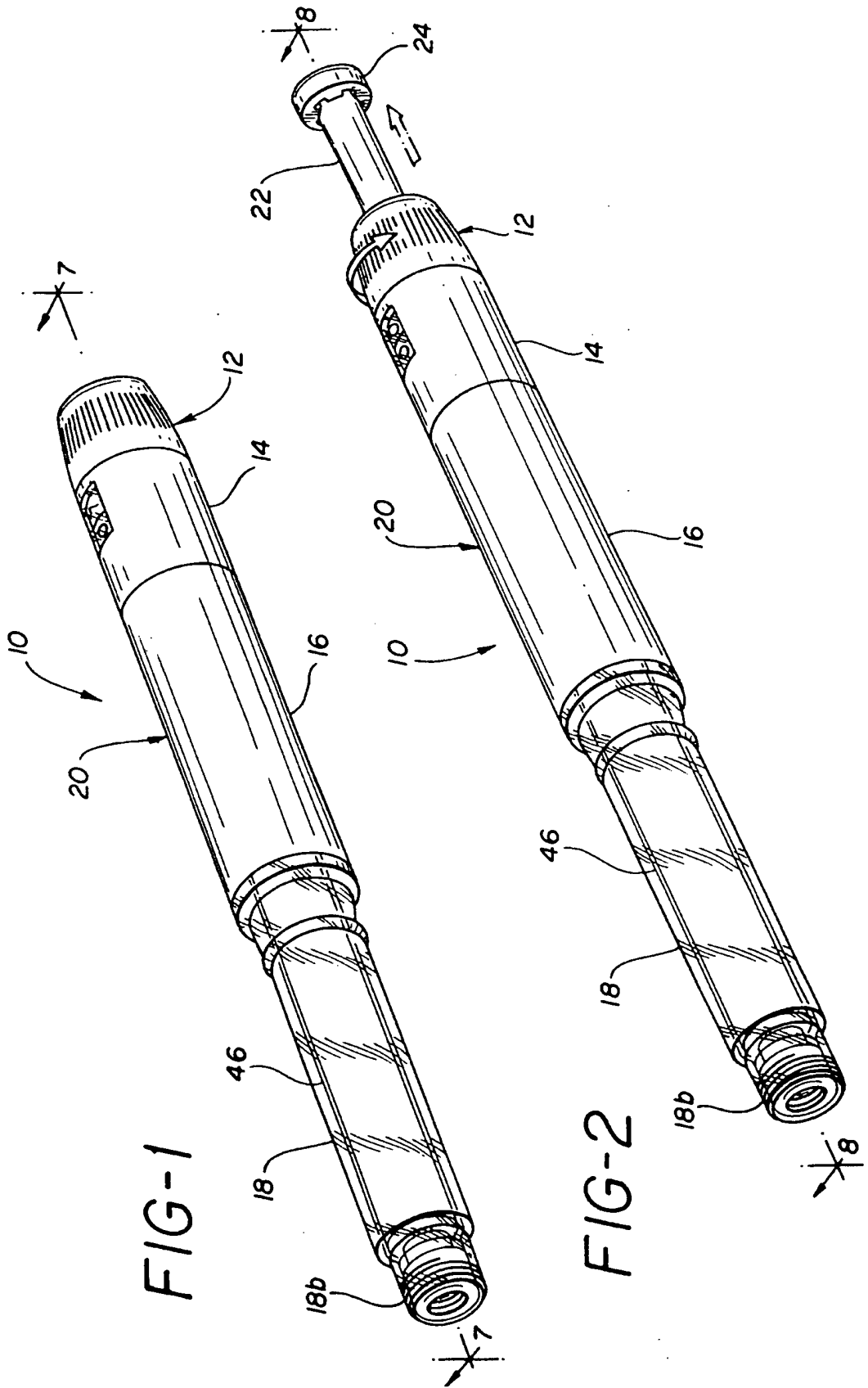
laquelle ladite partie taraudée desdits demi-écrous (28) est en contact avec ladite vis conductrice (26).

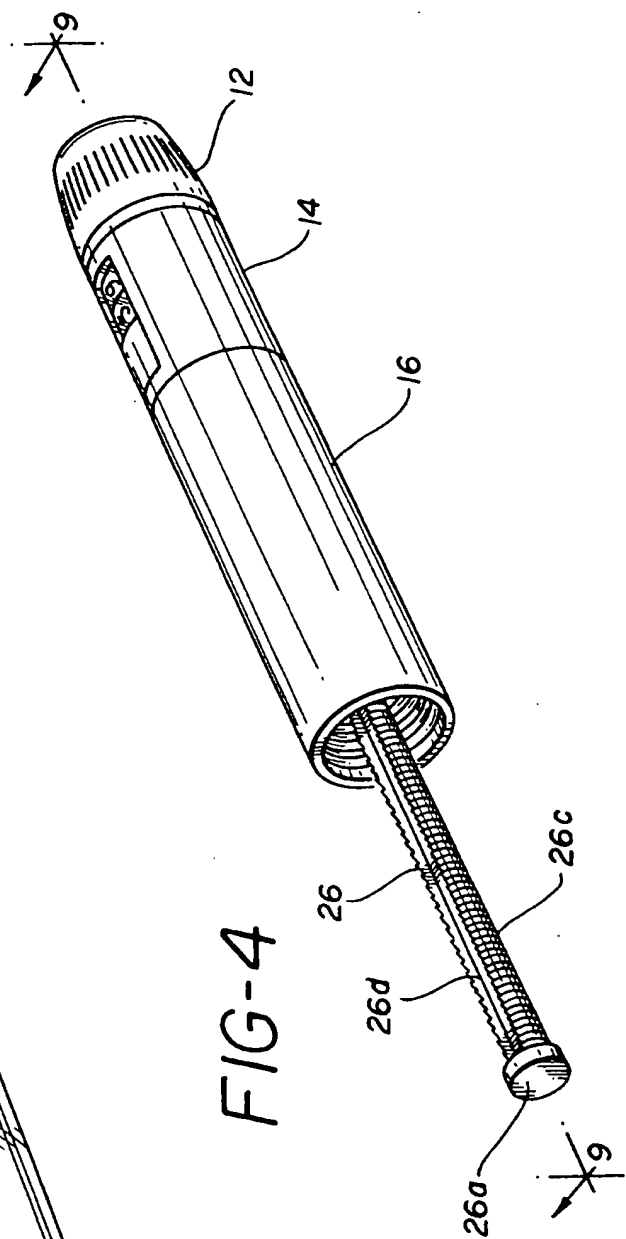
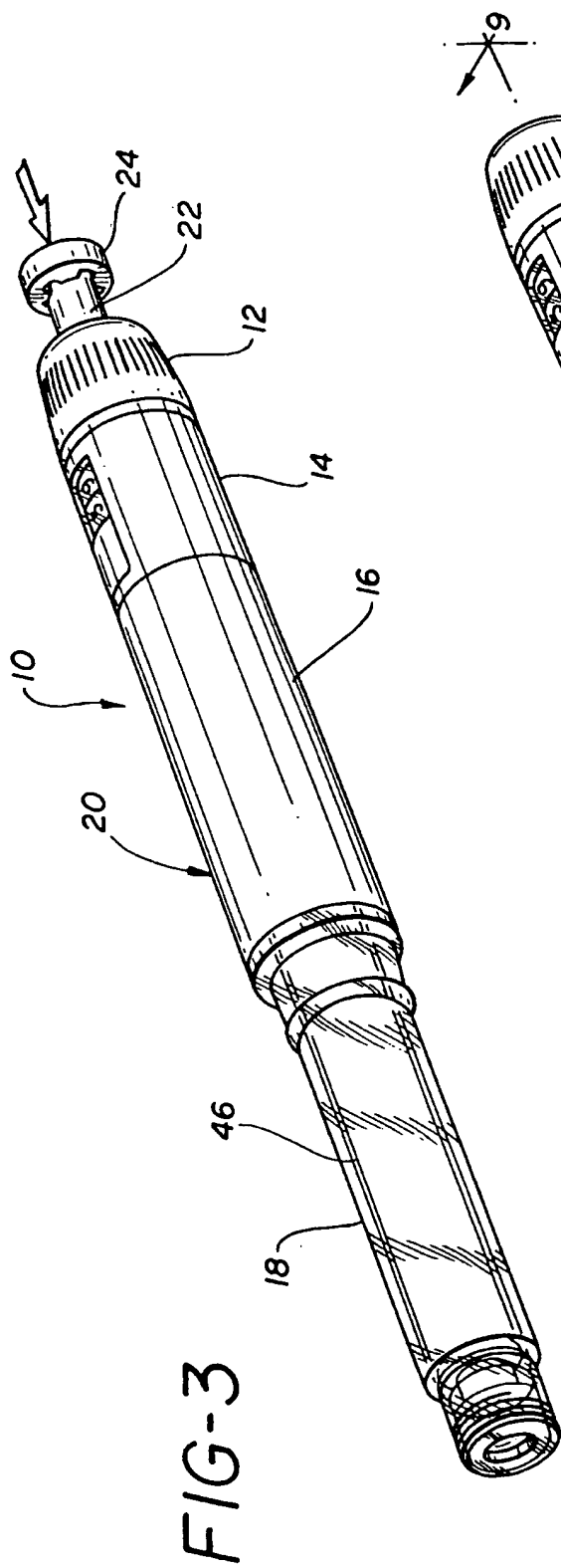
8. Dispositif d'injection (10) selon la revendication 1, comprenant en outre:

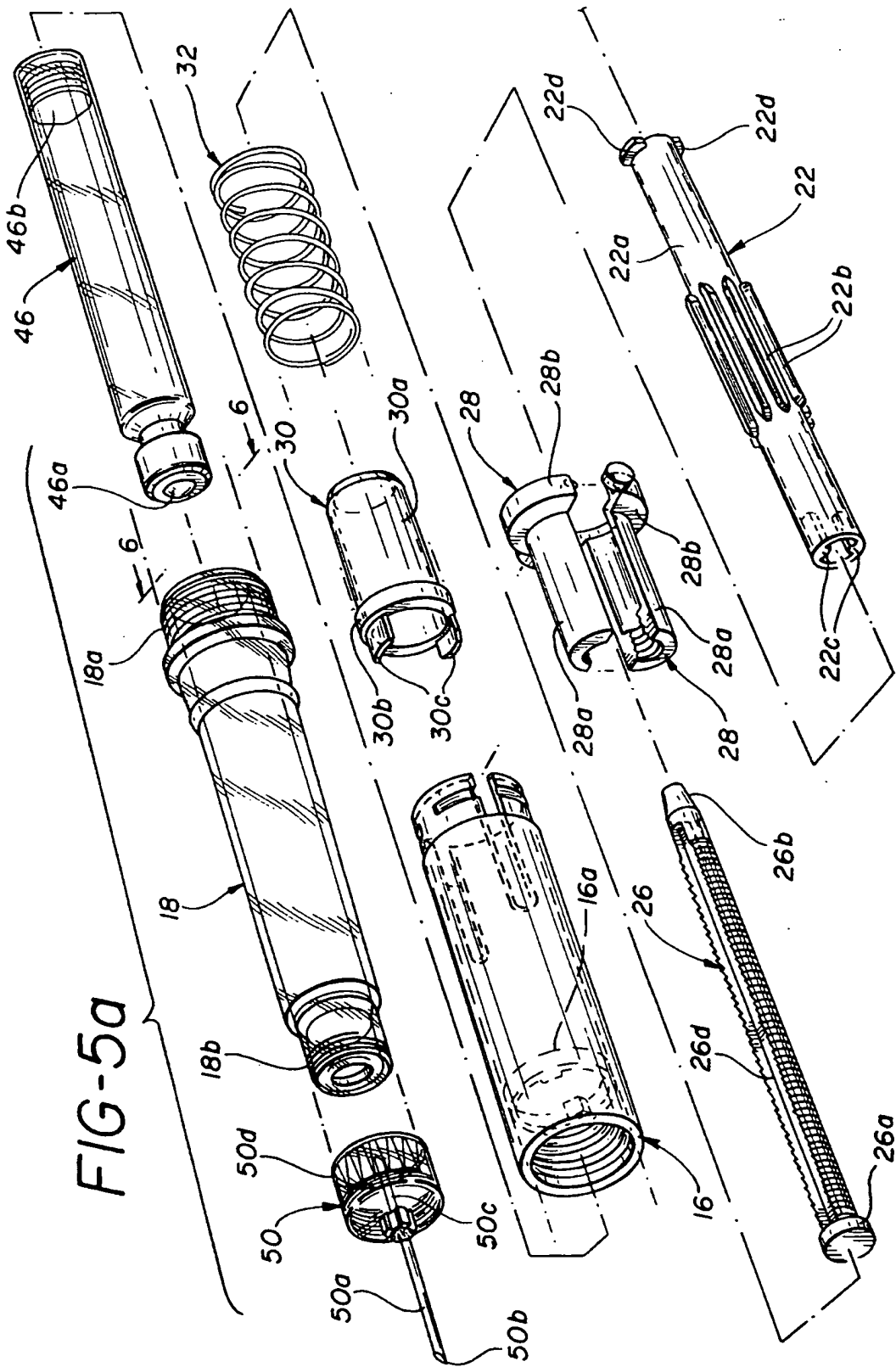
une partie d'élément-plongeur (22) de ladite tige-piston (22, 26, 28) placée au moins partiellement à l'intérieur de ladite enveloppe (18);
 une partie de vis conductrice (26) de ladite tige-piston (22, 26, 28) placée au moins partiellement à l'intérieur dudit élément-plongeur (22) et pouvant glisser axialement dans celui-ci;
 un moyen pour visser ladite vis conductrice (26);
 un moyen pour coupler et désaccoupler sélectivement ledit moyen pour visser ladite vis conductrice (26) avec ladite vis conductrice (26), ladite vis conductrice (26) pouvant glisser librement par rapport audit élément-plongeur (22) lorsque ledit moyen pour visser ladite vis conductrice (26) est désaccouplé de ladite vis conductrice (26), ladite vis conductrice (26) et ledit élément-plongeur (22) pouvant glisser comme une unité par rapport à ladite enveloppe (18) lorsque ledit moyen pour visser ladite vis conductrice (26) est couplé avec ladite vis conductrice (26).

9. Dispositif (10) selon la revendication 8, dans lequel ledit moyen pour visser ladite vis conductrice (26) comprend une paire de demi-écrous (28) au moins partiellement filetés placés de manière opposée l'un par rapport à l'autre à l'intérieur de ladite enveloppe (18), la partie taraudée de chaque demi-écrou faisant face à ladite vis conductrice (26).

10. Dispositif (10) selon la revendication 9, dans lequel ledit moyen pour déplacer lesdits demi-écrous (28) comprend une bague de blocage (30) rotative, ladite bague de blocage (30) ayant une paroi intérieure elliptique, dans lequel la rotation de ladite bague de blocage (30) amène ladite paroi intérieure de ladite bague de blocage (30) à se mettre en contact avec lesdits demi-écrous (28) et à déplacer lesdits demi-écrous (28) dans une position dans







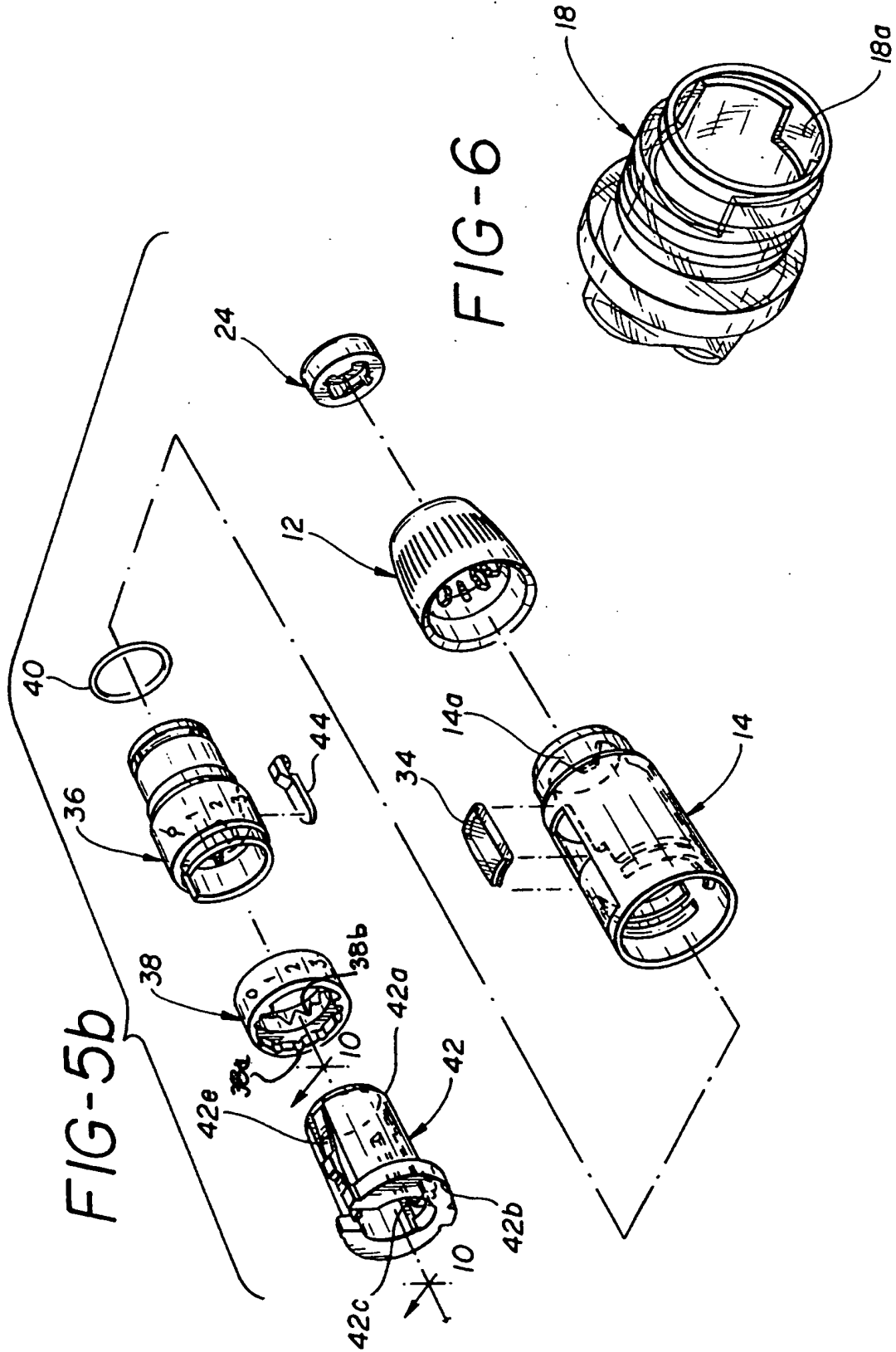


FIG-7

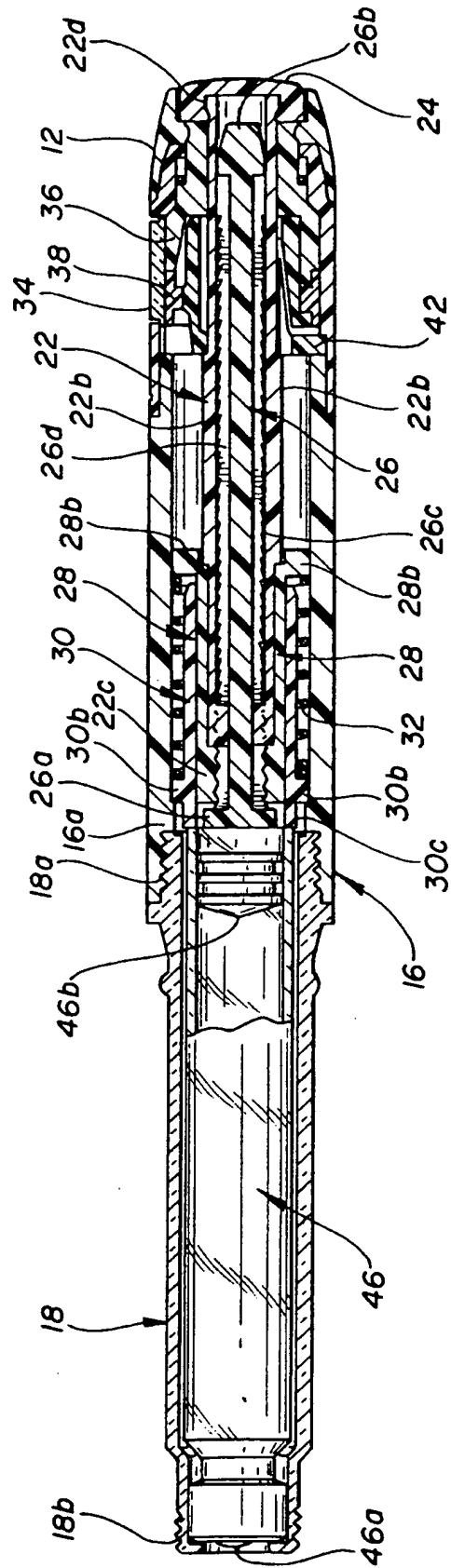


FIG-8

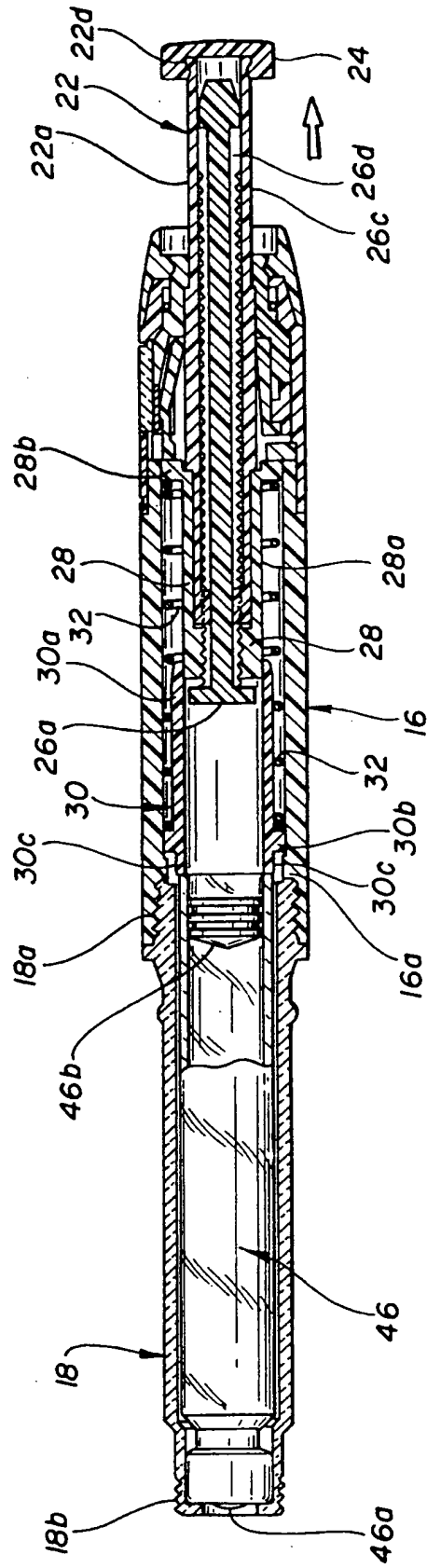


FIG-9

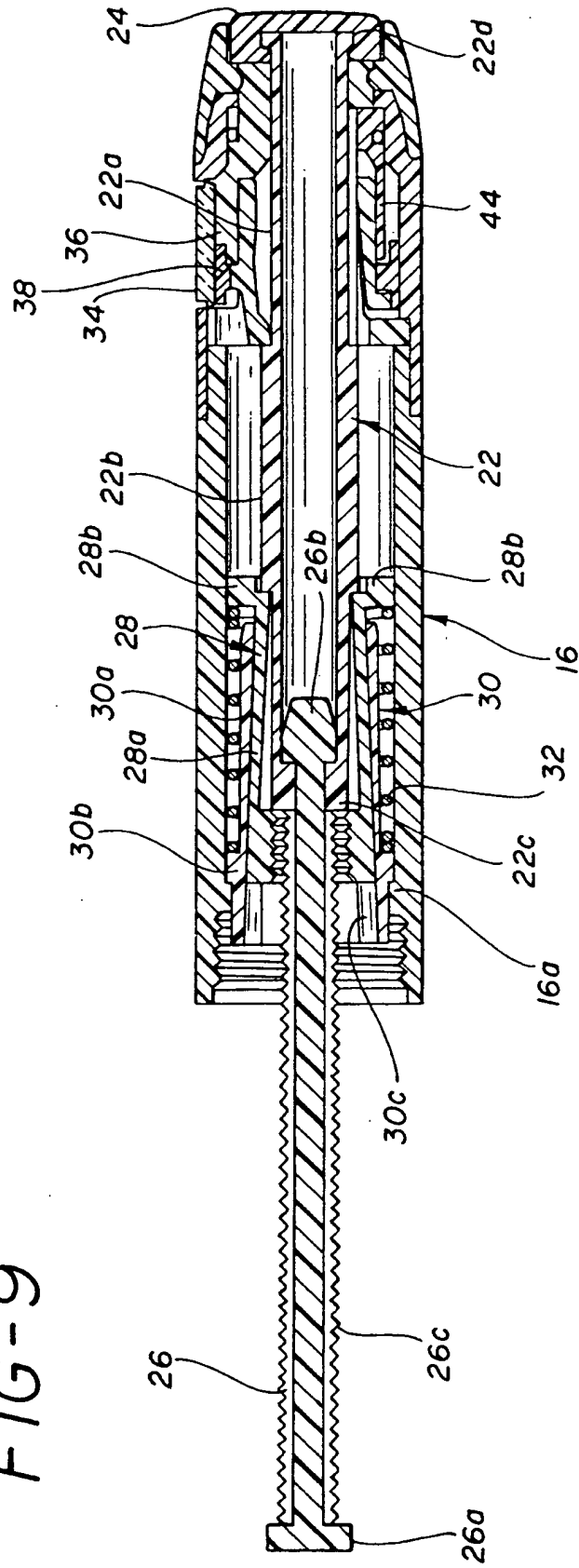


FIG-10

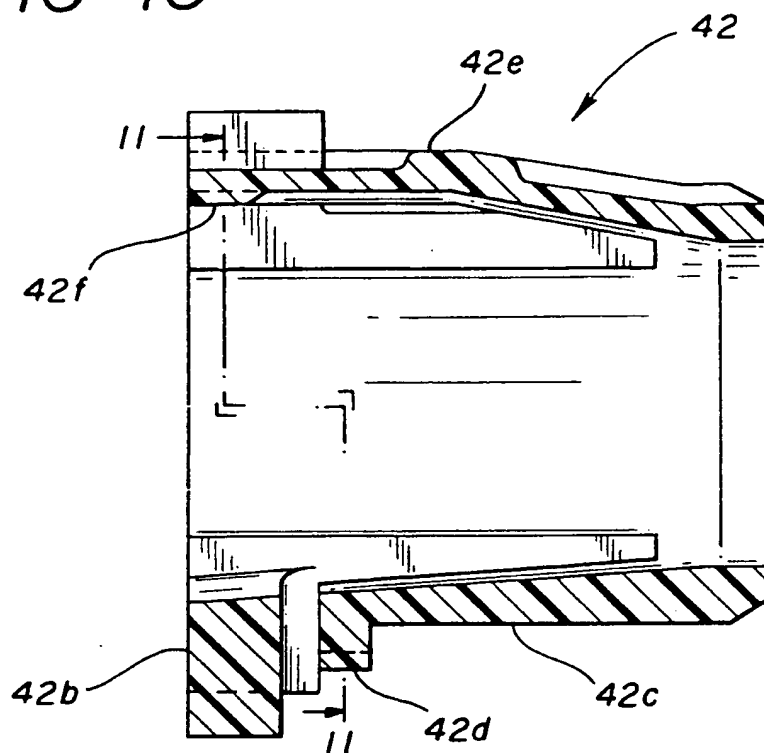


FIG-11

